

REMARKS**Rejection of Claims 10, 19, 25, 31 and 39 under 35 U.S.C. §112, first paragraph**

Claims 10, 19, 25, 31 and 39 are rejected under 35 U.S.C. §112, first paragraph “because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description” (Office Action, page 2). Noting Applicants’ remarks in the Amendment received in the U.S. Patent and Trademark Office (PTO) on October 24, 2003 (the “previously filed Amendment”), the Examiner states that the rejection is maintained because “a copy of the email confirming the deposit of monoclonal antibody 26-10 has not been received” and “it is not clear from Applicant’s remarks whether the deposit was made after the application was filed” (Office Action, page 2). The Examiner reminds Applicants that certification of such a deposit must be made and that the specification must be amended to refer to the deposit.

As noted in the previously filed Amendment, the hybridoma that expresses the anti-digoxin monoclonal antibody 26-10 (specification, page 16, lines 4-10) has been previously deposited under the provisions of the Budapest Treaty with the American Type Culture Collection (ATCC) Accession No. HB-8120, and is now publicly available. The deposit of hybridoma 26-10 was made with the ATCC on March 31, 1982, prior to the filing of the subject application. Ms. Marie Harris of the ATCC Patent Department confirmed the deposit and public availability of monoclonal antibody 26-10 in an e-mail to Applicants’ Attorney dated October 20, 2003. A copy of the e-mail, which was filed as the Exhibit in the previously filed Amendment, was received by the U.S. PTO on October 24, 2003. A copy of the postcard that was filed with the previously filed Amendment and date stamped by the U.S. PTO on October 24, 2003, and another copy of the Exhibit from the previously filed Amendment (*i.e.*, the e-mail from Ms. Harris) are being filed herewith for the Examiner’s convenience.

The specification has been amended to refer to the deposit as required under 37 C.F.R. §1.809(d). Statements under 37 C.F.R. §1.806 and §1.808 are being filed concurrently, completing the formal requirements for a biological deposit, thereby obviating the rejection.

Accordingly, Applicants have provided an enabling disclosure for the full scope of the claimed invention.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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Dated: *February 22, 2005*



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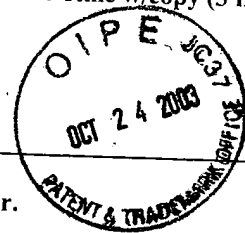
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Docket No.: 2075.1002-003

Date: October 21, 2003

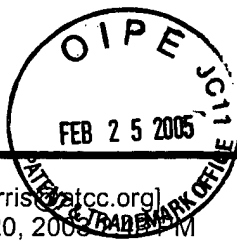
This is to acknowledge receipt of the following documents each filed under Certificate of Mailing Procedure 37 C.F.R. 1.8:

☒ Amendment/Reply Fee Letter w/copy ☒ Pet Ext Time w/copy (3 month)
☒ AMENDMENT
____ AMENDMENT AFTER FINAL ACTION
☒ Check for \$ 475.00 _____ Auth to charge fees
____ REPLY TO OFFICE ACTION
☒ Other _____ Exhibit



Applicant: Rex T. Gallagher and Garner T. Haupt, Jr.
Application No.: 09/506,246 Filed: February 17, 2000
Title: Process for Large-Scale Isolation and Purification of Hypothalamic Inhibitory Factor
Date received by the PTO:

Anne Collins



COPY

From: Harris, Marie [Mharris@atcc.org]
Sent: Monday, October 20, 2003 7:48 PM
To: Anne Collins
Cc: 'rmenapace@partners.org'; Nunnally, Tanya
Subject: ATCC No. HB-8113 and HB-8120

Dear Ms. Collins,

For your information, ATCC No. HB-8113 (deposited as Antidigoxin Hybridoma, Dig 35-20 on January 29, 1982) and HB-8120 (deposited as Antidigoxin Hybridoma, Dig-26-10 on March 31, 1982) are now available for distribution.

These items can be obtained by contacting the ATCC Customer Service Department. The items are not listed on the ATCC website. Only those items

that have been authenticated by the ATCC are available on the ATCC website.

If you have any questions please feel free to contact me.

Sincerely,
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